UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

R.S.B., a minor, by and through his Parent and Next Friend, Stephanie Hammar, and STEPHANIE HAMMAR, Individually,

Plaintiffs,

v. Case No. 20-C-1402

MERCK & CO., INC. and MERCK SHARP & DOHME CORP.,

Defendants.

DECISION AND ORDER GRANTING DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiff R.S.B., a minor, by and through his parent, Stephanie Hammar, brought this action against Defendants Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively "Merck"), alleging that R.S.B.'s use of Merck's product, Singulair®, and its generic form, montelukast, caused him to suffer neuropsychiatric injuries. Plaintiffs assert claims of strict liability design defect, strict liability failure to warn, and negligence. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. Before the Court is Merck's motion for summary judgment on all claims related to R.S.B.'s use of the generic montelukast, which Merck neither manufactured nor sold. For the reasons that follow, Merck's motion will be granted.

BACKGROUND

Merck was granted U.S. Patent No. 5,565,473 for an asthma medication named Singulair in 1996 after discovering the anti-asthmatic properties of montelukast, Singulair's active ingredient. 2d Am. Compl. ¶ 20, Dkt. No. 29. Under its patent, Merck was the exclusive

manufacturer, distributer, and seller of Singulair. *Id.* ¶ 13. In 1998, the FDA approved New Drug Applications (NDA) for Merck to sell Singulair as 10 mg tablets and chewables, and in 2002, the FDA approved an NDA for Singulair oral granules. Pls.' Statement of Fact (PSOF) ¶¶ 1–3, Dkt. No. 44. When Merck's patent expired in 2012, generic manufacturers began producing montelukast. 2d Am. Compl. ¶ 13. Approximately 9.3 million patients received a montelukast prescription in United States outpatient pharmacies in 2018, and 2.3 million of these patients were less than 17 years old. *Id.* ¶ 21.

R.S.B. was prescribed Singulair to treat his asthma and hay fever symptoms from December 2010 to August 2012. *Id.* ¶ 7. From August 2012 through January 2015, R.S.B. received generic montelukast, which was manufactured by TEVA Pharmaceuticals. PSOF ¶ 51. The parties dispute whether R.S.B. exhibited any neuropsychiatric symptoms while taking Singulair. Merck asserts that R.S.B.'s medical records do not reveal any mention of problems possibly associated with montelukast until 2015, but Plaintiffs allege that "R.S.B. became symptomatic while he was using Merck's Singulair®." 2d Am. Compl. ¶ 9. In 2019, Hammar testified before the Food and Drug Administration (FDA) that her son began suffering "severe neuropsychiatric side effects" in 2014 after his montelukast dosage was increased from five to ten milligrams. Tr. of Joint Mtg. of the Pediatric Advisory Comm. & Drug Safety and Risk Mgmt. Advisory Comm. 71, FDA (Sept. 27, 2019), https://www.fda.gov/media/132560/download.

In any event, Plaintiffs allege that, as a direct and proximate result of ingesting Singulair, R.S.B. was admitted to a psychiatric inpatient facility for suicidal and homicidal thoughts and was ultimately diagnosed with Major Depressive Disorder; Anxiety Disorder; Obsessive-Compulsive Disorder; Ego-Dystonic; intrusive thoughts about homicide, suicide, and sex; and poor coping. 2d Am. Compl. ¶ 8. Plaintiffs assert that R.S.B.'s neuropsychiatric events are identical or akin to

those now included on Singulair's warning label, and that he suffered more severe injuries as a result of the cumulative effect of using Singulair and generic montelukast. *Id.* ¶¶ 8, 11, 20.

Plaintiffs assert that montelukast crosses the blood-brain barrier (BBB), which is a semi-permeable membrane of endothelial cells that prevents solutes in circulating blood from non-selectively entering the extracellular fluid and thereby interacting with neurons in the central nervous system. *Id.* ¶ 25. The BBB protects the brain from circulating pathogens and renders bloodborne brain infections rare. *Id.* No antibodies, only certain antibiotics, and exceedingly few drugs may pass the BBB and have an impact on the central nervous system. *Id.* ¶ 26. Plaintiffs claim that, because montelukast crosses the BBB, it exerts a systemic effect upon the central nervous system that results in adverse neuropsychiatric events. Plaintiffs further allege that the risk of new neuropsychiatric events is greater in pediatric patients. *Id.* ¶¶ 31, 38. In 2020, after reviewing adverse event data involving montelukast, the FDA required sellers of montelukast to add a black box warning related to the risk of mental health side effects to its label. PSOF ¶ 46. Plaintiffs claim that Merck knew of the increased risk of neuropsychiatric injuries to pediatric patients at the time R.S.B. began taking Singulair but failed to provide adequate warnings.

Although R.S.B. only used Merck's product Singulair for the period from December 2010 to August 2012, Plaintiffs claim that Merck is liable for injuries R.S.B. sustained over the entire period he used either Singulair or montelukast from December 2010 through January 2015. The current complaint includes three separate claims. Counts One and Two allege product liability claims for defective design and failure to warn, respectively. Count Three alleges common law negligence in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of their product and in the failure to provide adequate warnings. In its motion for summary judgment, Merck seeks a determination that it has no liability for any

injury RSB sustained from ingesting the generic montelukast Merck neither manufactured nor sold.

LEGAL STANDARD

Federal Rule of Civil Procedure 56(a) allows a party to move for summary judgment on particular claims or defenses, or part of those claims or defenses. "Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment 'shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Anderson v. Liberty Lobby*, 477 U.S. 242, 247 (1986). "By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Id.* at 247–48 (emphasis in original). "When the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 576 (1986). Under the Rule, "the nonmoving party must come forward with 'specific facts showing that there is a *genuine issue for trial*.'" *Id.* at 587 (quoting Fed. R. Civ. P. 56(e)) (emphasis added in *Matushita Elec.*). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Id.*

ANALYSIS

Merck has moved for summary judgment, asserting that it is not liable under any of the three counts listed in Plaintiffs' second amended complaint for injuries related to R.S.B.'s use of generic montelukast. Plaintiffs do not dispute Merck's argument that Merck is entitled to summary

judgment on Plaintiffs' strict liability design defect and failure to warn claims (Counts One and Two) with respect to injury R.S.B. sustained from ingesting generic montelukast. Plaintiffs do contend, however, that Merck may be liable for negligent misrepresentation as the drafter of the generic montelukast label as alleged in Count Three.

In essence, Plaintiffs maintain that Merck can be found liable under the theory of "innovator liability." Under this theory of liability, at least as it relates to this case, a brand-name drug manufacturer may be held liable for misrepresentations on the product label of its own brand-name drug as well as the generic equivalents of its brand-name drug. The rationale for this type of liability arises from the duties imposed upon the different kinds of drug manufacturers. While a brand-name manufacturer "bears responsibility for the content of its label at all times," *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009), a generic drug manufacturer may only change its generic drug label when it updates the label to "match an updated brand-name label or to follow the FDA's instructions." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 614 (2011). Because a generic drug label may only be updated in these two limited circumstances, Plaintiffs assert that Merck, as the author of Singulair's warning label, should be held liable for the generic montelukast's allegedly deficient warning label. Based upon the briefs of the parties and the Court's own research, it seems that no Wisconsin court has addressed the theory of "innovator liability." But the Court need not reach the question of whether the Wisconsin Supreme Court would adopt this theory because Plaintiffs' negligent misrepresentation claim for injury caused by a product it did not manufacture or sell is barred by Wisconsin's product liability statute, Wis. Stat. § 895.046.

In enacting Wis. Stat. § 895.046, the Wisconsin Legislature found that it was "in the public interest to clarify product liability law, generally," and to return tort law to its "historical, common law roots." Wis. Stat. § 895.046(1g). In doing so, the legislature sought to ensure that "businesses

may conduct activities in this state without fear of being sued for indefinite claims of harm from products which businesses may never have manufactured, distributed, sold, or promoted, or which were made and sold decades ago." *Id.* To implement these policies, the legislature made the statute applicable to:

> all actions in law or equity, whenever filed or accrued, in which a claimant alleges that the manufacturer, distributor, seller, or promoter of a product is liable for an injury or harm to a person or property, *including actions based on allegations that the design, manufacture, distribution, sale, or promotion of, or instructions or warnings about*, a product caused or contributed to a personal injury or harm to a person or property, a private nuisance, or a public nuisance, *and to all related or independent claims*, including unjust enrichment, restitution, or indemnification.

Wis. Stat. § 895.046(2) (emphasis added). As to such products, the statute provides two avenues for relief. Under § 895.046(3), a claimant must prove, "in addition to any other elements required to prove his or her claim, that the manufacturer, distributor, seller, or promoter of a product manufactured, distributed, sold, or promoted the specific product alleged to have caused the claimant's injury or harm." Wis. Stat. § 895.046(3).

If identification of the specific product is not possible, then a claimant may pursue relief under § 895.046(4), the "risk-contribution" theory, which allows the claimant to hold a manufacturer, distributor, seller, or promoter of a product liable without specifically identifying the product, so long as the claimant proves (1) "that no other lawful process exists for the claimant to seek any redress from any other person from the injury or harm;" (2) "that the claimant has suffered an injury or harm that can be caused only by a manufactured product chemically and physically identical to the specific product that allegedly caused the claimant's injury or harm;" and (3) "that the manufacturer, distributor, seller, or promoter of a product manufactured, distributed, sold, or promoted a complete integrated product, in the form used by the claimant or to which the claimant was exposed." Wis. Stat. § 895.046(4). The product must also meet three

additional requirements involving chemical and physical identity; the geographic market and time period in which the product was manufactured, distributed, sold, or promoted; and whether the product was distributed or sold without labeling or any distinctive characteristic that identified the manufacturer, distributor, seller, or promoter. *See* Wis. Stat. § 895.046(4)(a).

Plaintiffs assert that § 895.046 does not apply because their negligent misrepresentation claim is not a product liability claim. But the language of the statute makes clear that it applies to all actions in law or equity, in which a claimant alleges that a company is liable for injury or harm to a person "based on allegations that the design, manufacture, distribution, sale, or promotion of, or instructions or warnings about, a product caused or contributed to a personal injury" and to all related or independent claims. *See* Wis. Stat. § 895.046(2). In other words, it is not limited to strict liability claims. Here, Plaintiffs' complaint contains allegations of design defect, failure to warn, and negligence. Plaintiffs' claims for design defect and failure to warn are encompassed by § 895.046(2), and as a result, § 895.046 also applies to the *related claim* of negligent misrepresentation. *See Frase v. Ashland Chem. Co. Div. of Ashland, Inc.*, No. 19-cv-273-wmc, 2020 WL 1974190, at *3 (W.D. Wis. Apr. 24, 2020) (finding that § 895.046 encompassed all of the plaintiffs' claims, including a claim for negligence).

Plaintiffs assert that § 895.046 only applies to claims involving the "risk-contribution theory," a theory Plaintiffs maintain they are not pursuing here. Plaintiffs argue that the legislature merely sought to limit liability under the risk-contribution theory and that it was simply "over-inclusive" in describing the statute's applicability. Dkt. No. 42 at 23. While the legislature *did* limit liability under the risk-contribution theory by enacting § 895.046(4), it also made clear that claims alleging personal injury caused by the use of a product sold in the state could not otherwise be brought against parties that were not the manufacturer, seller or promoter of the product alleged

to have cause the plaintiff's injury. In other words, in enacting § 895.046, the legislature intended not only to narrow the application of risk-contribution theory in the State; it also intended to "clarify product liability law, *generally*" and "to return tort law to its historical, common law roots." Wis. Stat. § 895.046(1g) (emphasis added).

It thus follows that § 895.046 applies to Plaintiffs' claims, including their claim of negligence. That section provides two paths to recovery for injury alleged to have been caused by a product: one under § 895.046(3) against the actual manufacturer, seller, distributor, or promoter of the product that allegedly caused the injury and a second, where the manufacturer, seller, distributor, or promoter cannot be identified, under § 895.046(4) relating only to the risk-contribution theory. *See Frase*, 2020 WL 1974190, at *3 (noting that § 895.046 contemplates a products liability claim proceeding under one of two distinct liability theories, and that § 895.046(4) represents the risk-contribution theory). Because Plaintiffs admit that their claims do not involve the risk-contribution theory, Dkt. No. 42 at 24, Plaintiffs only road to recovery is under § 895.046(3).

Plaintiffs contend that even in the event the Court determines § 895.046 applies, their negligence claim nevertheless survives under § 895.046(3) because Merck promoted the sale of generic montelukast. Under the statute, Plaintiffs must prove, "in addition to any other elements required to prove [their] claim, that the manufacturer, distributor, seller, or promoter of a product manufactured, distributed, sold, or promoted the specific product alleged to have caused the claimant's injury or harm." Wis. Stat. § 895.046(3). Plaintiffs contend "regardless of whether Merck wanted to do so, Merck promoted the generic Singulair manufactured by a drug company and used by RSB." Dkt. No. 42 at 24. Plaintiffs claim that, because generic companies do not market their drugs, they effectively rely on Merck to do all of the promotion through its

"advertisements, detail people, hired guns at speakers' bureaus, publications in the Orange Book and so on." *Id.* Plaintiffs note that brand-name drug manufacturers typically decrease advertising just prior to the expiration date of the patent, allegedly because the brand-name manufacturer knows that its advertisements will serve to promote sales for the generic manufacturers as well. *Id.* at 25. Plaintiffs contend that, because Merck "promoted" the generic montelukast, Plaintiffs meet the requirements of § 895.046(3).

Acceptance of this argument would render § 895.046(4) meaningless because potential plaintiffs could always make the showing that a defendant promoted its own product and therefore qualifies as a promoter of all other products within the same category. Put simply, just because two businesses compete in the same space and advertise their own products does not mean that the businesses, by promoting their own product, are promoting the products of their competitors. A bike manufacturer, for example, may advertise the latest model of its own mountain bike, but because the advertisement may promote mountain bikes generally does not mean that the advertisement can be considered the promotion of a *competitor's* mountain bike. A company, no matter what precarious position it may be in, does not intend to promote a competitor's product to the detriment of its own sales. The same is true of here. Merck is not promoting generic montelukast or the chemical composition of the drug when it promotes Singulair; it is promoting Singulair itself—the brand-name version of the drug produced by Merck. To assert that Merck is promoting generic montelukast is to assert that Merck is promoting the products of its direct competitors to the detriment of its own product. This line of logic belies basic business principles and would render § 895.046(4) meaningless. *See Belding v. Demoulin*, 2014 WI 8, ¶ 17, 352 Wis. 2d 359, 843 N.W.2d 373. ("Statutory interpretations that render provisions meaningless should be avoided.").

In sum, § 895.046 applies to Plaintiffs' claim for negligent misrepresentation. Plaintiffs have failed to show that Merck "manufactured, distributed, sold, or promoted the specific product alleged to have caused the claimant's injury or harm," namely, the generic montelukast. *See* Wis. Stat. § 895.046(3). Therefore, Plaintiffs' negligent misrepresentation claim relating to R.S.B.'s use of generic montelukast fails.

CONCLUSION

For the foregoing reasons, Merck's motion for summary judgment as to all claims alleging injury from generic montelukast (Dkt. No. 35) is **GRANTED**. Plaintiffs' strict liability design defect, strict liability failure to warn, and negligent misrepresentation claims, to the extent they encompass injuries allegedly caused by generic montelukast, are dismissed.

SO ORDERED at Green Bay, Wisconsin this 27th day of December, 2021.

s/ William C. Griesbach
William C. Griesbach
United States District Judge